

**Notice of Allowability**

Application No.

10/524,960

Examiner

Joseph Kosack

Applicant(s)

BUSH ET AL.

Art Unit

1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Response to Non-Final Rejection filed 11 August 2006.
2. ☒ The allowed claim(s) is/are 3-6, 27 and 29.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### **DETAILED ACTION**

Claims 2-6, 27 and 29 are pending in the instant application.

#### ***Amendments***

The amendment filed on August 11, 2006 has been acknowledged and has been entered into the record.

#### ***Previous Claim Objections***

Claim 6 was objected to as being a substantial duplicate of claim 2 in the action mailed on April 18, 2006. Applicant has correctly stated that they are in fact different claims as 2 was drawn to any one peak and claim 6 was comprising all peaks. Therefore, the objection is withdrawn.

#### ***Previous Claim Rejections - 35 USC § 112***

Claims 21-32 (previously 22-33) were rejected under 35 U.S.C. 112, first paragraph in the action mailed on April 18, 2006 for not meeting the enablement requirement. Applicant has amended the claims to delete the subject matter that was not enabled, and the rejection is withdrawn.

#### ***Previous Double Patenting Rejections***

Claims 1, 7, and 21-32 (previously 22-33) were rejected on the grounds of non-statutory double patenting as unpatentable over copending App No. 10/488,519 in view of SmithKline Beecham Corp. v. Apotex Corp. Claims 1, 7, 21-26, 28 and 30-33 have been cancelled, and claims 27 and 29 are not dependent upon the product in the '519 case. Therefore, the rejection is withdrawn.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tina M. Tucker on August 28, 2006.

The application has been amended as follows:

Delete claims 2 and 9.

In claim 27, line 4, delete "2" and insert ---3---.

In claim 29, line 4, delete "2" and insert ---3---.

***Reasons for Allowance***

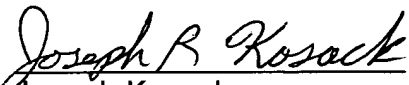
The present invention is drawn to a crystalline form of biphenyl-4-carboxylic acid (R)-(6-(1-((4-fluorobenzyl)methylaminoethylideneamino)-2(R)-hydroxyindan-1-yl)amide hemihydrate and methods of use. The closest prior art teaches the compound in its anhydrous form, but does not teach the specific crystalline form claimed by the instant invention. Therefore, claims 3-6, 27, and 29 are allowed.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 5:30 A.M. until 2:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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Joseph K. M<sup>c</sup>Kane  
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